REMARKS

Upon entry of this amendment, claims 5, 9, 12-14, 39, 42, and 50-61 are pending in the instant application. Claim 61 has been amended. The present amendments are fully supported by the specification and the claims as originally filed. For example, support for the amendment to claim 61 is found at least at page 4, lines 26-30 Accordingly, no new matter has been added.

Claim Rejections Under 35 U.S.C. § 101

The Examiner has maintained the rejection of claims 5, 9, 12-14, 39, 42 and 50-61 under 35 U.S.C. § 101 for lack of utility. According to the Examiner, "the claimed nucleic acid has a specific sequence structure but the disclosed uses are not specific for the claimed nucleic acids" and "the disclosed uses are generally applicable to broad classes of this subject matter." (Office Action, page 3).

Applicants traverse this rejection as well as the characterization that the disclosed uses are "generally applicable to broad classes" of the claimed subject matter. The pending claims are directed to isolated nucleic acids encoding the polypeptide of SEQ ID NO:14 (or a mature form thereof), to isolated nucleic acids comprising SEQ ID NO:13 (or the complement thereof) and to specific variants of these nucleic acids.

The as-filed specification discloses that these claimed nucleic acids are useful in differentiating certain cancer tissues from the corresponding normal (*i.e.*, non-cancerous) tissues, *e.g.*, in diagnostic tests. In particular, the specification discloses that the claimed nucleic acids are present at elevated levels in certain types of prostate cancer (*see e.g.*, Table 12DD on page 223, columns 4-6, line 13) and certain types of lung cancer (*see e.g.*, Table 12DE on page 224, columns 1-3, lines 15-22), including at least one strain of small cell lung cancer (*see e.g.*, Table 12DF on page 226, columns 1-3, line 2). Thus, the nucleic acids of the claimed invention are useful as cancer markers for specific types of cancers -- namely certain types of prostate cancers, lung cancers and small cell lung cancers. The level of expression of these specific nucleic acids in a biological sample, such as a sample from a tumor or suspected tumor, is detected and compared to the expression level of these nucleic acids in the corresponding normal tissue. Thus, the utility of the claimed nucleic acid molecules is specific, rather than "generally applicable to broad classes" of nucleic acids. This utility depends upon the particular nucleic

acids recited by the claims presented herein, and is, therefore, specific for the claimed nucleic acids.

Moreover, the use of the claimed nucleic acids in differentiating certain cancer tissues from the corresponding normal tissue is credible. Applicants submit that the skilled artisan, in light of the data presented in Tables 12DD through 12DF, would find this asserted utility believable. The logic underlying this assertion is sound, and the facts upon which this assertion is based are consistent with the logic underlying this assertion.

Furthermore, the use of the claimed nucleic acids as diagnostic tools for certain types of cancers is substantial. Detection of cancer using the claimed nucleic acid molecules as markers for certain types of prostate cancers, lung cancers and small cell lung cancers, is a desirable outcome based upon a need in the art. Thus, the skilled artisan would appreciate that measurement of the relative amount of nucleic acid in tumor tissue as compared to normal adjacent tissue, *e.g.*, by using the method provided in Example 2 or by another well established method, is useful as a real-world tool in cancer diagnosis. Such expression tests are currently commercially available in the U.S., thereby demonstrating a substantial and credible "real world" utility for an invention of this type.

Applicants submit, therefore, that the as-filed specification provides a specific, substantial and credible utility for the claimed nucleic acids as markers for specific types of cancer, *e.g.*, in diagnostic tests for certain prostate cancers, lung cancers and small cell lung cancers. Accordingly, the claim rejections under 35 U.S.C. § 101 should be withdrawn.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 5, 9, 12-14, 39, 42 and 50-61

The Examiner has rejected claims 5, 9, 12-14, 39, 42 and 50-59 under 35 U.S.C. § 112, first paragraph. According to the Examiner, one skilled in the art would not know how to use the claimed invention because it is not supported by either a specific or substantial asserted utility or a well established utility.

Applicants traverse. For the reasons given above, the claimed nucleic acids are supported by a specific, substantial and credible utility as markers for specific types of cancer. Accordingly, this rejection should be withdrawn.

Claims 51-53 and 57-61

Claims 51-53 and 57-61 have been rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the invention at the time the application was filed. According to the Examiner, "it is unclear what activity the claimed variants possess, what activity the claimed encoded proteins possess and therefore unclear how a person having skill in the art would have used the claimed variants." (Office Action, page 4).

The nucleic acids and nucleic acid variants recited by claims 51-53 and 57-61 are described throughout the specification as originally filed. For example, the variants recited by amended claims 51-53 and 57-61 are disclosed, *e.g.*, on page 294 of the as-filed specification. Thus, the claims are literally supported by the as-filed disclosure in the instant application. Moreover, as described above, the nucleic acids of the claimed invention share a common function, namely the ability to differentiate certain cancer tissues, *e.g.*, certain types of prostate cancers, lung cancers and small cell lung cancers, from the corresponding normal tissue. Thus, the claims presented herein recite unique structural and functional limitations for the genus of nucleic acids recited by claims 51-53 and 57-61.

Accordingly, Applicants submit that the claims presented herein are sufficiently described by the as-filed specification in such a manner as to allow a person skilled in the art to conclude that Applicants had possession of the claimed invention at the time of filing. Applicants, therefore, request that the Examiner withdraw this rejection.

Claim Rejections Under 35 U.S.C.§ 102

Claim 61 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Oohashi *et al.*, J. Cell Biol., vol. 145(3):563-77 (1999)) ("Oohashi"). In particular, the Examiner has indicated that the Oohashi reference describes a "protein having 97.6% sequence identity to SEQ ID NO:14". (Office Action, page 5).

Claim 61 has been amended herein to recite a variant of an isolated nucleic acid molecule encoding a polypeptide of SEQ ID NO:14 (or a mature form thereof), wherein the variant comprises a nucleic acid sequence encoding an amino acid sequence that is at least 99% identical to the amino acid sequence of SEQ ID NO:14.

In contrast to the nucleic acids recited by amended claim 61, the Oohashi reference does not teach or suggest a variant of a nucleic acid encoding either a polypeptide of SEQ ID NO:14 or a mature form thereof, wherein the variant nucleic acid sequence encodes an amino acid sequence that is at least 99% identical to the amino acid sequence of SEQ ID NO:14. As such, this fails to disclose every element of the claimed invention. Accordingly, amended claim 61 is novel over the Oohashi reference, and this rejection should be withdrawn.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529
Attorney for Applicant
c/o MINTZ, LEVIN
Tel: (617) 542-6000
Fax: (617) 542-2241
Customer No. 55111

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